REMARKS

Favorable reconsideration of this application is requested in view of the above amendments and the following remarks.

Claims 9-10 and 16-18 have been canceled without prejudice.

Claims 1 and 11 have been amended as supported by examples 1-4 of the specification on pages 5-7. Please note that examples 2-4 of the specification include a lake pigment, which provides a color but does not affect the material properties of the composition such as an enteric film coating of claims 1 and 11. Claim 3 has been amended as supported by the specification at page 4, lines 16-19. Claim 5 has been amended as supported by the specification at page 4, lines 12-15. Claims 2, 4, 6-8, and 12-15 have been amended editorially.

Claims 1-8, 11-15, and 18 haven been rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. (U.S. Patent Application Publication No. 2004/0028737) in view of Mehra et al. (U.S. Patent No. 5,733,575). Applicants respectfully traverse this rejection.

Applicants note that Whittle et al. is referred to in the Examiner's response to arguments (see page 3 of the Office Action mailed September 9, 2011). Applicants assume that the Whittle reference merely is cited as a support for the use of sodium hydroxide (NaOH) as a stabilizer in the Office Action and is not a basis of the rejection. However, independent claims 1 and 11 are distinguished from the composition of Whittle, which includes NaOH, for the same reasons as discussed against Deshpande, particularly example 7 of Deshpande, below.

Claim 1 is directed to a non-toxic, edible, enteric film coating, dry powder composition that consists essentially of a methacrylate copolymer of Type C, a plasticizer, a film coating detackifier, and an opacifier. The claim recites that the dry powder composition of claim 1 does not contain any alkalinizing agent. The ingredients

of the composition recited in claim 1 necessarily include the methacrylate copolymer of Type C, plasticizer, film coating detackifier, and opacifier. The composition of claim 1 may include unlisted ingredients that do not materially affect the properties of the composition of claim 1 such as the enteric coating properties. Without including the alkalinizing agent, which can neutralize free acid groups such as free carboxylic acid groups in the composition by forming a salt, the conventional enteric coating cannot be resistant to the acidic environment in a stomach sufficiently (see page 3, lines 1-9 of the specification). In contrast, the composition of claim 1 can provide the resistance to the stomach environment similar to the conventional composition including the alkalinizing agent despite not including the alkalinizing agent (see *id.*).

As the rejection admits, example 7 of Deshpande includes sodium hydroxide (NaOH) (see page 4 of the Office Action and paras. [0063]-[0064] on pages 4-5 of Deshpande). Deshpande teaches that the acidic pH may be adjusted with an alkali such as NaOH, potassium hydroxide, etc. (see para. [0038] on page 2). From Deshpande's teaching, those skilled in the art would understand that an alkali such as NaOH adjusts pH by neutralizing the acid present in the composition for forming a salt as defined in the present specification, and that thus NaOH is an alkalinizing agent excluded from the composition of claim 1 (see page 3, lines 1-9).

In addition, the rejection asserts that NaOH can be a buffering agent and/or stabilizing agent in addition to the pH adjusting agent (see page 4 of the Office Action). This is irrelevant. The buffering or stabilizing agent and pH adjusting agent can change the pH of the composition. For example, Deshpande teaches that when the pH of the composition is increased over pH 6, the viscosity of a methacrylate polymer solution in the enteric coating composition can be extremely increased (see para. [0027] on page 2). Thus, NaOH can affect the properties of the enteric coating formed with the composition of Deshpande materially (see also, page 3, lines 1-9 of the specification). Accordingly, claim 1 is distinguished from the composition of example 7 in Deshpande, which includes NaOH excluded from claim 1.

Moreover, the rejection asserts that example 5 of Deshpande does not include NaOH (see page 4 of the Office Action). In the Office Action, the outer coating layer of the reference alone is compared with the enteric film coating composition of claim 1 (see

page 4 of the Office Action). Applicants respectfully disagree. Examples 5-7 and 9 of Deshpande have a two-layer coating, which includes a barrier coating, i.e., an inner coating having pH 7-7.5, and an outer coating having pH 2-6, such as pH 3.0 (examples 5-6 and 9) or pH 5.0 having been adjusted with NaOH (example 7) (see abstract and examples 5-7 and 9 on pages 4 and 5). Deshpande teaches that the enteric coating is a bilayer enteric coating having a pH gradient, which is obtained by the inner layer and outer layer (see paras. [0024]-[0025] on page 2). The reference further teaches that the preferable enteric coating has the neutral or near neutral pH inner layer up to $1/4^{th}$ of the enteric coating thickness and the acidic pH outer layer up to $3/34^{th}$ of the enteric coating thickness (see *id.*).

Accordingly, the combination of the inner layer and outer layer of examples 5-7 and 9 of Deshpande forms the enteric coating layer, and the combination of the two layers should be compared with the enteric film coating composition of claim 1.

For example, in example 5 of Deshpande, the inner layer includes polyvinylpyrrolidone K-30 in addition to talc and polyethylene glycol (see para. [0058] on page 4). Polyvinylpyrrolidone may be used as a viscosity modifier in a pharmaceutical composition, which can help the coating to adhere to a tablet surface and make the coating suspension thicker, and polyvinylpyrrolidone can act as a suspending agent of the coating and a film former (see coln. 4, lines 32-48 of Mehra). Thus, polyvinylpyrrolidone would affect the properties of the enteric film coating materially, and polyvinylpyrrolidone also is excluded from the composition of claim 1.

In addition, the enteric film composition of claim 1 can provide excellent delayed-release profile of the active ingredient as one layer without including the alkalinizing agent, for example 0.1 % after two hours in 0.1 HCl at 37°C and greater than 85 % in 45 minutes in phosphate buffer (pH 6.8) (see examples 1-5 on pages 5-7, particularly second para. on page 6, of the specification). There is no reasonable basis to assume that such release profile can be obtained with the composition of example 5 in Deshpande if example 5 had the outer layer alone and no inner layer. Accordingly, claim 1 is distinguished from example 5 of Deshpande.

With respect to examples 1-4 and 8 of Deshpande, these examples include an ammonia solution to neutralize pH of the composition i.e., an alkalinizing agent as

defined in the present specification (see paras. [0045], [0049], [0053], [0057], and [0068] on pages 3-5 of Deshpande and page 3, lines 1-9 of the specification). Thus, claim 1 also is distinguished from examples 1-4 and 8 of Deshpande.

Mehra is directed to a non-toxic enteric film coating dry powder composition (see abstract). Mehra teaches that the enteric film coating composition includes an alkalinizing/anti-coagulant agent and lists candidate materials for the alkalinizing agent such as a bicarbonate, carbonate, phosphate, or hydroxide of sodium or potassium, etc. (see *id.* and coln. 3, lines 52-56). Accordingly, Mehra does not remedy the deficiencies of Deshpande.

If Mehra were combined with Deshpande, there is no reasonable basis to assume that sodium hydroxide (NaOH), which is characterized as the alkalinizing agent in Mehra, would not be considered as the alkalinizing agent in the combination of the references as the rejection asserts (see page 4 of the Office Action).

Further, Deshpande teaches that examples 1-4 and 8, which include an ammonia solution to neutralize the coating, have higher resistance to acid penetration compared with examples 5-7 and 9, which have the bi-layer enteric coating as discussed above (see para. [0079] on page 6). Even if Deshpande and Mehra were combined as asserted in the rejection, there is no reasonable basis that those skilled in the art would use the bi-layer enteric coating such as example 5 in Deshpande, instead of examples 1-4 and 8 of Deshpande including the ammonia solution to neutralize the coating, with the dry powder form taught by Mehra.

Accordingly, claim 1 and its dependent claims 2-8 and 12-15 are distinguished from Deshpande in view of Mehra.

Similar to claim 1, claim 11, which is directed to a method of making a dry powder enteric film coating composition, recites the ingredients of the composition that consist essentially of the methacrylate copolymer of Type C, plasticizer, a film coating detackifier, and opacifier. Claim 11 further recites that the composition does not contain any alkalinizing agent, also similar to claim 1. Thus, for at least the same reasons as discussed for claim 1 above, claim 11 also is distinguished from Deshpande in view of Mehra.

Accordingly, this rejection should be withdrawn.

Claims 9, 10, 16, and 17 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. (U.S. Patent Application Publication No. 2004/0028737) in view of Mehra et al. (U.S. Patent No. 5,733,575) and Kokubo et al. (U.S. Patent No. 4,948,622. Claims 9-10 and 16-17 have been canceled. Accordingly, this rejection is moot and should be withdrawn. Applicants do not concede the correctness of the rejection.

In view of the above, Applicants request reconsideration of the application in the form of a Notice of Allowance.

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